

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicants' reply to the Examiner's June 8, 2009 Final Office Action. Claims 8, 10, and 11 are amended and Claim 14 is currently cancelled. Claims 1, 2, 4-7, and 12 remain withdrawn. Accordingly, Claims 8, 10, and 11 are under examination in view of the above amendments.

Applicants believe that no new matter has been added with regard to the claim amendments provided herein. Applicants do not donate or disclaim any claims or subject matter with the claim amendments made herein, and the Applicants expressly reserve the right to prosecute the original claims or any unclaimed subject matter in one or more future filed continuing applications.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicants' arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Objection to Priority Claim and Oath/Declaration

The Examiner objected to the priority claim to Korean Application No. 10-2003-0002314, as not being referred to in the Declaration or Application Data Sheet. In response, Applicants submit a new executed Declaration form and an Application Data Sheet,

which claim the full priority of the present application. Additionally, Applicants also amend the Specification to include a statement cross-referencing the priority applications.

II. Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected Claim 14 under 35 U.S.C. § 112, first paragraph, as failing to provide enablement for the full scope of the claims. Applicants have cancelled Claim 14 in an effort to expedite allowance of claims. However, Applicants do not acquiesce to the Examiner's rejection of this claim. Applicants' cancellation of this claim makes the Examiner's rejection moot.

III. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claims 8, 10, 11, and 14 under 35 U.S.C. § 112, second paragraph, for not particularly pointing out and distinctly claiming the subject matter of the invention. Applicants have amended claims 8 and 11 have been amended to overcome this rejection and are now in allowable form. Claim 10 has been amended to clarify its wording and is dependent upon now allowable Claim 8. Accordingly, Claim 10 should now also be allowable. Applicants have cancelled Claim 14 in an effort to expedite allowance of the claims.

IV. PRIOR ART REJECTIONS

A. Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 8, 10, and 11 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,183,737 to Zaleske et al. ("Zaleske") in view of Bouhadir et al. (Biotechnol Prog. 2001, "Bouhadir").

The Examiner admitted the exemplified method of Zaleske differs from the present application in that Zaleske applies fibrin glue as the biological gel to adhere the cartilage matrices and to fill gaps at the interface(s) between matrices. Further, while the fibrin glue may be considered a semi-permeable agent that forms a semi-permeable membrane on an outer

surface of each of the scaffolds, Zaleske does not teach further adding a cross-linking agent, as fibrin does not require cross-linking.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined. Secondary considerations may also be utilized in this analysis to give light to the circumstances surrounding the origin of the subject matter sought to be patented. KSR Int'l Co., 82 USPQ 2d at 1391. When making any obviousness rejection, the Examiner must first acquire a thorough understanding of the claimed invention by reading the specification and claims to understand what the Applicant is claiming as his invention. MPEP § 904.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit.) See MPEP § 2142. “Rejections on obviousness cannot be sustained with mere conclusory statement; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” See MPEP § 2142; In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a 103(a) rejection, the examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52

(Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121

(Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

Amended Claim 8 currently reads as:

A method of preparing a biological tissue, comprising:

seeding cells obtained from a tissue to be regenerated onto one or more scaffolds having an outer surface to produce a scaffold piece having a thickness of between about 1 to 3 mm;

loading a plurality of said scaffold pieces into a molding container having a predetermined form and size and having a morphology of a tissue to be regenerated;

adding a semi-permeable agent selected from the group consisting of alginates, polysaccharides, chitosan, and agar powder and a cross-linking agent to the molding container, to form by a cross-linking thereof, a semi-permeable membrane, permeable to nutrients;

gelating a semi-permeable agent on a surface of each of the scaffold pieces loaded in the molding container to interconnect the scaffold pieces with each other through the semi-permeable membrane; and

introducing nutrients into the scaffolds interconnected with the semi-permeable membrane.

The molding container in the present invention is suitable to form the biological tissue being produced. Therefore, the molding container has the morphology of a tissue to be regenerated thereby it has a predetermined form and size. But, unlike the present invention, the Petri dish of Zaleske, corresponding to the molding container in the present invention, is directly used for providing a space for loading cartilage cell-seeded matrices.

Furthermore, the Petri dish in Zaleske does not have the form and size of the biological tissue having the morphology to be regenerated. On the other hand, the molding container according to the present invention could be changed in form and size depending on the biological

tissue being produced. Accordingly, the present invention cannot be obvious based on Zaleske and/or Bouhadir.

As such, Applicant requests these rejections to Claims 8, 10, and 11 be withdrawn.

The Examiner rejected Claims 8, 10, 11, and 14 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Publication No. 2005/0288796 to Awad et al. ("Awad") in view of Bouhadir.

The Examiner stated that this is a new rejection necessitated by the addition of Claim 14. Applicants have cancelled Claim 14 in an effort to expedite allowance of claims. However, Applicants do not acquiesce to the Examiner's rejection of this claim. Applicants' cancellation of this claim makes the Examiner's rejection moot.

Notwithstanding and in addition to the above, the molding container as disclosed in the present application has a predetermined form and size for forming the biological tissue being produced. In contrast, Awad is inapplicable because the prior art does not suggest a particular molding container having a predetermined size and form and having the morphology of a tissue to be regenerated so that it is suitable to form the biological tissue being produced. The prior art cannot be read as teaching or suggesting that one could reasonably be expected to manifest the claimed elements and properties.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Applicants herewith submit a Request for Continued Examination with the appropriate small entity fee. Applicants believe no additional fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 08-2665.

Respectfully submitted,

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